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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,177	01/29/2001	Ake Lindahl	003300-696	2132

21839 7590 07/15/2003

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/15/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/700,177

Applicant(s)

AKE LINDAHL

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04/22/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 11-20,22,23,26-28 and 41-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20,22,23,26-28 and 41-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Examiner acknowledges request for extension of time, amendment D and request for continued examination filed 04/22/03. The request for extension of time and terminal disclaimer filed 02/24/03 is also received. Claims 11-20, 22, 23, 26-28 and 41-56 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/22/03 has been entered.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 11-20, 22, 23, 26-28 and 41-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farinas et al. (US 5,906,830).

Farinas discloses a method for preparing transdermal drug delivery systems containing supersaturated drug reservoirs (abstract). The drug is heated to a temperature just higher than the calculated depressed melting temperature (column 6, lines 12-21). Farinas discloses that an amount of drug molecule is dispersed in the reservoir material at a concentration that is greater

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than the solubility of the drug in the reservoir material at room temperature to give a supersaturated drug reservoir (column 5, lines 1-10). The components of the reservoir include polymeric materials selected from polysiloxanes, polyacrylates and polyurethane adhesives (column 6, line 61 to column 7 line 24). Drugs that may be incorporated in the drug delivery system are narcotic agonists and antagonists, serotonergic agonists, antihistamines, anti-inflammatory agents, benzodiazepines, dopaminergic agonists and antagonists, hormones and antipsychotic agents (column 7, lines 39-64). The drug formulation further includes carriers or vehicles selected from stabilizers, antioxidants, anti-irritants, cellulosic polymers, polyvinyl alcohol and polyacrylic acid. See also claims 1-14. The teachings of Farinas anticipate the claims.

The method of Farinas comprises mixing polymeric material and a drug formulation, removing the most of the solvent, evaluating the depressed melting temperature of the drug-polymer mixture, heating the mixture to a predetermined temperature and cooling the heated mixture to form the supersaturated reservoir (claim 1). The invention does not teach any particular method steps.

Farinas does not specifically teach a chemical process. However, heating a reaction has the potential of eliciting a chemical reaction and this knowledge is within the purview of one of ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Farinas. One having ordinary skill in the art would have been motivated to prepare a supersaturated drug delivery reservoir according to the method of Farinas by heating with the expectation that the heat step would generate a chemical reaction that would result in a supersaturated drug formation.

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Applicants argue that Farinas uses heat to create supersaturation and the invention uses a chemical means to create supersaturation. However, it is within the knowledge of the ordinary or skilled artisan that heat can lead to chemical reaction.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
Patent Examiner  
Tech. Center 1600  
July 14, 2003

